REF YB500034	**TGS TA TOXO IgG Avidity**	
INSTRUCTIONS FOR USE **EN** *English*	IVD +2°C +8°C Σ 50	CE 0459

INTENDED USE

The *TGS TA TOXO IgG* Avidity test is a chemiluminescent immunoassay (CLIA) for determination, using *TGS TA Analyser* or *IDS-iSYS Multi-Discipline Automated System*, of Avidity Index of specific IgG class antibodies directed against the Toxoplasma gondii (TOXO) in samples of human serum or plasma (EDTA, Sodium Citrate).
The possibility of differentiating antibodies at high avidity from low avidity allows to supply interesting clinical information. This assay is used as a diagnostic aid when assessing immunity status of patients related to Toxoplasmosis.
This product must be used in strict compliance with the instructions given in this document by professional users.

CAUTION: Medical decisions must not be based exclusively on the result of this test, but must take into account all available clinical and laboratory data as a whole.

CLINICAL SIGNIFICANCE

Toxoplasmosis is a parasitic disease caused by infection with the obligate intracellular protozoan *Toxoplasma gondii*[1]. The parasite infects most genera of warm-blooded animals, including humans, but the primary host is the felid (cat) family. Animals are infected by eating infected meat, by ingestion of feces of a cat that has itself recently been infected, and by transmission from mother to fetus[2]. Cats are the primary source of infection to human hosts, although contact with raw meat, especially pork, is a more significant source of human infections in some countries. Fecal contamination of hands is a significant risk factor [3]. Toxoplasmosis is one of the most chronic infections affecting one third of the world's human population[4]. The prevalence of Toxoplasma gondii infection varies among different geographical regions. The infection is characterized by non-specific symptoms with the consequent formation of cysts that may remain in latent form in many organs[5.] Primary infection is usually subclinical but in some patients cervical lymphadenopathy or ocular disease can be present[6]. There are four groups of individuals in whom the diagnosis of toxoplasmosis is most critical: pregnant women who acquire their infection during gestation, fetuses and newborns who are congenitally infected, immune compromised patients, and those with chorioretinitis[7,8,9]. Although these infections are usually either asymptomatic or associated with self-limited symptoms in adults (e.g., fever, malaise and lymphadenopathy), infections in pregnant women can cause serious health

problems in the fetus if the parasites are transmitted (i.e., congenital toxoplasmosis) and cause severe sequelae in the infant including mental retardation, blindness and epilepsy. The most frequent challenge encountered by physicians the world over is how to determine if a pregnant woman acquired the acute infection during gestation. Women who acquired their infection prior to pregnancy are essentially not at risk for delivering an infected infant (unless the woman is immunosuppressed). Furthermore, methods of diagnosis and their interpretations may differ for each clinical category.

The diagnosis of Toxoplasma gondii infection may be established by serologic tests, amplification of specific nucleic acid sequences (PCR), histological demonstration of the parasite and/or its antigens or by isolation of the organism[8]. The use of serologic tests for demonstration of specific antibody to Toxoplasma gondii is the initial and primary method of diagnosis. Serological screening relies on IgG and IgM antibody determinations. The presence of elevated levels of Toxoplasma specific antibodies indicates infection has occurred at some point, but does not distinguish between an infection acquired recently and one acquired in the distant past. In acute infection, IgG and IgM antibodies generally rise 1 to 2 weeks of infection[10]. Detection of Toxoplasma specific IgM antibodies is so used as an aid in determining the time of infection, but it is critical to remind that IgM antibodies have been reported to persist for up to 18 months post infection[11].

To differentiate between a recently acquired infection and a past infection, IgM and IgG positive specimens should be tested for IgG avidity. A high avidity index for IgG antibodies is a strong indication that an infection took place more than 4-5 months ago[12,13,14].

PRINCIPLE OF THE METHOD

The *TGS TA TOXO IgG* Avidity kit for qualitative determination of the avidity of specific anti-Toxoplasma gondii IgG employs an indirect two-step immunological method based on the principle of chemiluminescence. *The test can be done only by using samples previously tested to detect the presence of IgG anti Toxoplasma gondii*.

The specific antigen is used to coat the magnetic particles (solid phase) and an anti-human IgG antibody is labelled with an acridinium ester derivative (conjugate).

Each specimen is dispensed into two adjoining cuvettes: cuvette (a) as reference and (b) in which a buffer able to prevalently break the binding Antigen (Ag)- Antibody (Ab) if the antibody is at low avidity, is added . During initial incubation, the specific antibodies present in the sample, in the calibrators or in the controls bond with the solid phase. In the second cuvette (b) only, at the end of the first incubation, a second incubation is performed in a buffer able to break the binding between the Ag of the magnetic particles and the Antibodies IgG of the samples if they are present at low avidity. During the last incubation, the conjugate reacts with the anti-Toxoplasma gondii IgG antibodies captured by the solid phase.

After each incubation, the material that has not bound with the solid phase is removed by aspiration and subsequent washing.

The quantity of labelled conjugate that remains bound to the solid phase is assessed by activation of the chemiluminescence reaction and measurement of the light signal. The generated signal, expressed in relative light units (RLU), is indicative of the concentration of specific antibodies present in the sample, in the calibrators and in the controls. The ratio between the concentration of antibodies of the second cuvette (b)

(treated sample- IgG not removed) and the concentration of antibodies of the first cuvette (a) (not treated sample-Total IgG) is the Index of Avidity of the Antibodies IgG Anti Toxoplasma gondii present in the sample.

AUTOMATION

The *TGS TA Analyser* instrument automatically performs all the operations envisaged by the assay protocol: addition of samples, calibrators, controls, magnetic particles, conjugates and chemiluminescence activation solutions to the reaction cuvette; magnetic separation and washing of particles; measurement of the emitted light.
The system calculates the assay results for the samples and controls by means of a stored calibration curve and prints a report that includes all the information related to the assay and to the patient.

MATERIALS AND REAGENTS

Materials and reagents supplied

REAG	1	MP	2.5 mL

Magnetic particles coated with purified Toxoplasma gondii antigen in Phosphate Buffer containing stabilising proteins, Pro-Clin 300 and sodium azide (< 0.1%) as preservatives.

REAG	2	CONJ	25 mL

Mouse Monoclonal anti-human IgG antibody labelled with an acridinium ester derivative (conjugate), in Phosphate Buffer containing stabilising proteins, surfactant, Pro-Clin 300 and sodium azide (< 0.1%) as preservative.

REAG	3	DIL	25 mL

Sample Diluent Solution: Phosphate Buffer containing bovine serum albumin, a surfactant, an inert blue colouring agent, Pro-Clin 300 and Gentamicin SO_4 as preservatives.

REAG	4	BUF AV	15 mL

Buffer solution: Borate buffer containing the dissociating agent and Sodium Azide (< 0.1%) as preservative.

REAG	5	CAL A	1.6 mL

Human serum with low concentration of anti-Toxoplasma gondii IgG antibodies in Phosphate Buffer containing bovine serum albumin, a surfactant, an inert blue colouring agent, Pro-Clin 300 and Gentamicin SO_4 as preservatives.

REAG	6	CAL B	1.6 mL

Human serum with high concentration of anti-Toxoplasma gondii IgG antibodies in Phosphate Buffer containing bovine serum albumin, a surfactant, an inert blue colouring agent, Pro-Clin 300 and Gentamicin SO_4 as preservatives.

All reagents are ready for use.
Reagents 1, 2, 3 and 4 are assembled in a single reagents cartridge unit.
The Calibrator concentrations are expressed in IU/mL (International Units) and calibrated against International Standard 1st IS 01/600, 2003. The concentration settings, specific for each production lot, are recorded on the DATA DISK included in the kit.

DATA DISK

A Mini-DVD containing data regarding all the products in the TGS TA line (Reagents, Calibrators, Control Sera) updated to the last production lot with the exclusion of products that have expired at the date when the new DATA DISK was compiled.
Only the DATA DISK with the highest lot number needs to be kept to maintain the information required for correct operation of the system up to date.

Materials and reagents required but not supplied in the kit:

- TGS TA Analyzer 120 (1) — Cod. No. TGS00001
- IDS-iSYS Cuvette Cube (1) — Code No. IS-CC1000
  Pack of 960 cuvettes
- IDS-iSYS System Liquid (2) — Code No. IS-CS1000
  1 bottle containing 5 liters of ready-to-use solution.
- IDS-iSYS Wash Solution (2) — Code No. IS-CW1000
  1 bottle containing 10 liters of ready-to-use solution.
- IDS-iSYS Trigger Set (2) — Code No. IS-CT1000
  1 250 mL-bottle of Trigger A (pre-trigger solution)
  1 250 mL-bottle of Trigger B (trigger solution)
- TGS TA D-SORB Solution — Code No. YC500009
  Pack of 2 bottles containing 1 liter of ready-to-use solution.
- IDS-iSYS Cartridge Checking System (2) — Code No. IS-601000

- TGS TA ImmunoCleaner Code No. YC500012
  6 bottles each containing 27 mL

- TGS TA Top Cap Set Code No. YC500010
  300 red top caps to close the calibrator containers after first use.

(1) Manufactured by IDS France SAS, 42 rue Stéphane Mazeau, 21320 Pouilly en Auxois, France and distributed by Technogenetics Srl.
(2) Manufactured by da IDS SA, 101-103 rue Ernest Solvay, 4000 Liège, Belgique and distributed by Technogenetics Srl.

Other Recommended Reagents

TGS TA TOXO AVIDITY Control Set Code No. YB500041
Three 1.5 mL vials of Low-Moderate Avidity human serum and three 1.5 mL vials of human serum of High Avidity for anti-Toxoplasma gondii antibodies.

WARNINGS AND PRECAUTIONS

The reagents supplied in the *TGS TA TOXO IgG* Avidity kit are only for in vitro diagnostic use and not for in vivo use in humans or animals.
This product must be used in strict compliance with the instructions given in this document by professional users.
Technogenetics cannot be held responsible for any losses or damages caused by use not in conformity with the instructions supplied.

Safety precautions
This product contains material of animal origin and therefore must be handled as if it contains infecting agents.
This product contains components of human origin. All units of serum or plasma used to produce the reagents in this kit have been analysed with FDA-approved methods and found not to be reactive due to presence of HBsAg, anti-HCV, anti-HIV1 and anti-HIV2.
However, since no analysis method is able to guarantee the absence of pathogenic agents, all material of human origin must be considered to be potentially infected and handled as such.
In the event of damaged packaging or accidental leakage, decontaminate the area concerned with a diluted solution of sodium hypochlorite after putting on suitable personal protective equipment (overall, gloves, goggles).
Dispose of the material use for the clean-up and of the packaging involved in the leakage according to national regulations for disposal of potentially infected waste.
In the event of damaged packaging or accidental leakage, do not use the reagents to perform the assay.

Some reagents contain sodium azide as a preservative. Since sodium azide may react with lead, copper and leaded brass forming explosive azides in piping, it is recommended that reagents or waste are not poured down drains but are disposed of in compliance with the national regulations on disposal of potentially hazardous waste.

Operating precautions

Reliable results can only be obtained by strictly complying with these instructions and carefully following what is written in the operating manual for the instrument.

The reagents supplied in the kit must be used only with the TGS TA *Analyzer* system.

The components of the reagent cartridge must not be removed from the cartridge and reassembled.

Do not use the kit after its expiry date.

REAGENT PREPARATION

The reagents supplied in the kit are all ready for use.

REAGENT STORAGE AND STABILITY

Store the reagents supplied in the kit at 2-8°C in a vertical position in a dark place.

In these conditions, unopened reagent cartridge and calibrators are stable until the expiry date.

After opening, the reagent cartridge can be used for 60 days if kept in a refrigerator at 2-8°C or in the analyser.

After opening, the calibrators can be used for 60 days if kept in a refrigerator at 2-8°C and if they have not been left in the analyser for more than 6 hours per session.

Do not freeze the reagents and calibrators.

SAMPLE PREPARATION AND STORAGE

The assay must be performed on samples of human serum and plasma (EDTA – Sodium Citrate).

Use of lipaemic, haemolysed and turbid samples is not recommended.

If the assay is performed after more than 8 hours, separate the serum or the plasma from the clot, from the red blood cells and transfer the supernatant from the gel separating tubes to the secondary tubes.

Before being analysed, samples may be kept in a refrigerator at 2-8°C for a maximum of 7 days.

If the assay is to be performed after more than 7 days, store the samples frozen (< -20°C).

Avoid repeated freezing and thawing.

OPERATING PROCEDURE

Carefully follow the instructions given in the user manual of the instrument to obtain reliable analytical results.

Loading of reagents

All the reagents supplied in the kit are ready for use.

Before inserting the reagent cartridge in the system, the magnetic particle container must be horizontally agitated by rotation in order to ensure correct resuspension of the particles. Avoid generating foam when performing this operation.

Place the reagent cartridge in the reagent area of the instrument using the rack provided and leave it to be agitated for at least 40 minutes before use.

Positioning of the reagent cartridge simultaneously determines reading of the identification bar-code. If the cartridge label is damaged or if it is not readable, the reagent cartridge identification data can be entered manually.

The instrument automatically maintains the magnetic particles constantly agitated.

If the reagent cartridge is removed from the instrument, store it at 2-8°C in a vertical position in a dark place.

Loading of calibrators

TGS TA calibrators are ready for use. Leave the calibrators at room temperature for 10 minutes and then gently shake the contents, either manually or using a vortex, avoiding the formation of foam.

When using the calibrators for the first time, remove the guarantee seal and the white sealing cap before placing them in the analyser.

If the calibrators have already been used, the container will have a top cap (red cap) with no guarantee seal. Remove the red closing cap before placing them in the analyser.

Place the calibrators in the samples area of the analyser; see the analyser user manual on how to identify them in the analyser. Bar-code data must be entered manually if the label is damaged or if it is unreadable.

The IgG anti-Toxoplasma gondii antibody concentration in the calibrators are recorded in the DATA DISK and automatically transferred to the analyser.

At the end of the session, the calibrator containers must be closed with the top caps (red caps) provided and stored at 2-8°C until they are used again.

The calibrators can be used for a maximum of four times.

Loading of controls

Place the controls in the samples area of the analyser. See the analyser user manual on how to identify them in the analyser. If there is no bar-code on the control or if it is not readable, the control identification data must be entered manually. If TGS TA Controls are used, see the instructions for use provided. The IgG anti-Toxoplasma gondii antibody concentration in the TGS TA controls are recorded in the DATA DISK and automatically transferred to the analyser.

Loading of samples

Place the samples in the samples area of the analyser; see the analyser user manual on how to identify them in the analyser. If there is no bar-code on the sample or if it is not readable, the sample identification data must be entered manually.

Select the required parameters for each sample.

According to the concentration of Toxo IgG previously tested, 3 protocols are available. They can be selected in “analyte list” parameters according to the following scheme:

TOXO IgG concentration between 5 and 50 IU/mL TOXO Avidity IgG 5-50

TOXO IgG concentration > 50 IU/mL TOXO Avidity IgG>50

TOXO IgG concentration between 1.5 and 5 IU/mL TOXO Avidity IgG<5

Calibration

The *TGS TA Analyzer* instrument uses a memorised calibration curve (master curve), generated by the manufacturer for each lot of reagent cartridges.

The “master curve” parameters, together with the calibrator concentration settings, are stored in the DATA DISK and automatically transferred to the instrument’s database.

Calibrators A and B are used to recalibrate the “master curve” in both for the instrument used and for the reagents on board.

To recalibrate, analyse three replicates of the two calibrators (A and B) and one replicate of each control. The concentration obtained with the controls make it possible to validate the new calibration. Once recalibration of the “master curve” has been accepted and stored in memory, all subsequent samples can be analysed without any further calibration, except in the following cases:

- when a reagent cartridge with a new lot number is loaded into the instrument;
- when the controls do not fall within the range of acceptability;
- after instrument maintenance;
- when the validity of the recalibrated “master curve” has expired.

The validity of the recalibrated “master curve” for the *TGS TA TOXO IgG* Avidity kit is 21 days.

Recalibration management is handled automatically by the analyser.

Assay

Press the start button.

1. The system aspirates 100 µL of Sample Diluent, 20 µL of Magnetic Particles, 100 µL of Sample Diluent and 10 µL of sample or control (for the calibrators the positive serum is supplied prediluted with Sample Diluent and the volume aspirated is 110 µL). The aspirated solutions and suspension are dispensed into the reaction cuvette. Each sample and control is assayed in two different cuvettes (a) and (b).
2. The reaction cuvette is incubated in the rotor at 37°C for 10 minutes.
3. After this phase of incubation, the magnetic particles are separated and washed.
    3.1 Only in the second sample cuvette (b) 200 µL of Buffer Avidity are added and the cuvette is incubated in the rotor at 37°C for 10 minutes.
    3.2 After this phase of incubation, the magnetic particles are separated and washed.
4. 200 µL of conjugate are dispensed into the cuvette.
5. The reaction cuvette is incubated in the rotor at 37°C for 10 minutes.
6. After this last phase of incubation, the magnetic particles are separated and washed and the cuvette is transferred to the reading chamber.

7. The quantity of conjugate bonded to the solid phase, expressed in RLU, is directly proportional to the concentration of anti-Toxoplasma gondii IgG present in the sample.
8. The readings obtained are interpolated on the calibration curve and transformed into concentration and Avidity Index.

QUALITY CONTROL

To ensure the validity of the assay, control sera at differing avidity levels (at least one low-moderate avidity serum and one high avidity serum) must be measured every day in which assay is performed.
If individual laboratory practice so dictates, more frequent or more numerous controls may be performed for verification of assay results. Follow local quality control procedures.
If TGS TA control sera are used, the expected average concentration and the acceptability limits are those given on the DATA DISK included in the control set pack too.
If different control sera are used, before using them, the values expected with TGS TA reagents and system must be defined.
If the control values does not fall within the specified range of acceptability, the related assay results are not valid and the respective samples must be analysed again.
In this case, before repeating the tests, a recalibration procedure must be performed.

CALCULATION AND INTERPRETATION OF THE RESULTS

Calculation of the results

The concentration of the anti-Toxoplasma gondii IgG present in the samples that are being tested is automatically calculated by the system. The results can be viewed on the display or printed.
The concentrations are expressed in IU/mL.
Calculation of the analyte concentration in the sample takes place by interpolating the response obtained for each sample on a calibration curve calculated in accordance with a 4-parameter logistic fitting (4PL, Y weighted), periodically corrected according to the responses obtained for calibrators assay results.
Each sample and control is assayed in two cuvettes: (a) as reference and (b) in which a buffer is added in order to remove the low avidity IgG anti-CMV.
The avidity results are expressed in Index, the ratio between the concentration of the cuvette (b) and the cuvette (a), and are automatically calculated by the instrument.
For detailed information on how the system calculates the results, please see the analyser user manual.

Interpretation of the results

Values lower than 0.0 IU/mL are extrapolated values, the message “OMR-” and/or ORA appears and they are shown as “equal to 0.0 IU/mL”.

Values higher than 78 IU/mL are accompanied by the message “OMR+” and/or ORA and may retested according to protocol TOXO Avidity IgG >50.

The Avidity Value elaborated by the instrument is expressed in Index.

The results of the samples may be interpreted in the following way:

(Index)	Interpretation
≤ 0.10	The sample must be considered at Low Avidity IgG anti-Toxoplasma gondii
>0.10÷0.15	The sample must be considered at Moderate Avidity IgG anti-Toxoplasma gondii
> 0.15	The sample must be considered at High Avidity IgG anti-Toxoplasma gondii

The values reported above are indicative only. Each laboratory will establish its own reference intervals.

It is worth to highlight that a low avidity index suggests a recent infection contracted within four months from the sample collection, but this result does not confirm the diagnosis with certainty since some of the infected individuals may present, for several months, detectable levels of low avidity antibodies.

A moderate value of the avidity index does not exclude the possible occurrence of a recent infection, but can also indicate a past infection with partial maturation of the IgG avidity.

A high value of the avidity index can exclude that a primary infection has been contracted less than four months before the sample collection.

LIMITS TO THE ASSAY METHOD

For diagnostic purposes, the results obtained with the TGS TA TOXO IgG *Avidity* kit and the TGS TA *Analyser* system must be used together with the other clinical and laboratory data available to the physician.

Bacterial contamination of the sample and heat inactivation may influence the result of the dosage.

Heterophilic antibodies present in human serum samples may react with immunoglobulin-based reagents, causing interference with in vitro immunological dosages. Such samples may give rise to anomalous readings if analysed with the TGS TA TOXO IgG Avidity kit.

DIAGNOSTIC SPECIFICITY AND SENSITIVITY

By the use of TGS TA TOXO IgG, TGS TA TOXO IgM and TGS TA TOXO IgG Avidity kits it is possible to evaluate the patient immune status related to Toxoplasma infection.

In the following table are reported the serological profiles of the 3 tests TOXO IgG, TOXO IgM e TOXO IgG Avidity and their relative interpretation with respect to the parasite exposure:

IgG anti-Toxoplasma	IgM anti-Toxoplasma	IgG anti-Toxoplasma Avidity (2nd level test)	Interpretation
negative	negative	--	Non immune (Individual susceptible to infection)
negative	positive	--	Suspected acute primary infection
positive	positive	Low Avidity	Recent primary infection (last 4 months from sample collection)
positive	positive	High Avidity	Recent, previous Primary infection with IgM presence (more than last 4 months from sample collection)
positive	negative	High Avidity-	Past infection

Using the TGS TA TOXO IgG, TGS TA TOXO IgM, TGS TA TOXO IgG Avidity tests, the diagnostic specificity and sensitivity was assessed in the following population of selected samples, examined with different methods and classified according to the rule of general consensus:
139 non-immune patients
127 samples from 61 patients diagnosed as infected by Toxoplasma in monitoring and follow-up
41 samples from many patients known as infected more than 4 months from sample collection.

Following the interpretation given above, it was possible to work out the diagnostic specificity and sensitivity relating to each group under evaluation.

All 139 non-immune patients have shown both IgG and IgM values below cut-off by using methods TGS TA TOXO IgG and TGS TA TOXO IgM. The diagnostic specificity of methods for IgG and IgM related to non-immune patients was 100% (95% Confidence Interval: 95,9-100,0 %).

Among 168 samples (127 patients diagnosed as infected by Toxoplasma in monitoring and follow-up and 41 from many patients known as infected more than 4 months from sample collection), the method TGS TA TOXO IgG has shown 164 positive samples e 4 negative samples, so the sensitivity is 97,6% (95% Confidence Interval: 93,6%-99,2 %). 4 negative samples are of patients with on-going seroconversion.

Among 127 samples from patients diagnosed as infected by Toxoplasma in monitoring and follow-up, the method TGS TA TOXO IgM has shown 123 positive samples and 4 negative samples, so the diagnostic sensitivity was 96,9% (95% Confidence Interval: 91,6-99,0%).

By using TGS TA TOXO IgG Avidity kit, 100 samples from patients diagnosed as infected within last 4 months from sample collection in monitoring and follow-up were tested. 94 samples showed low avidity, 5 moderate avidity and 1 high avidity.

Among 41 samples from many patients infected more than last 4 months from sample collection, all had positive IgG levels showing diagnostic a sensitivity of 100%, positive IgM levels in 39% of patients (16/41) and all 41 samples tested by TGS TA TOXO IgG Avidity kit had high Avidity.

PERFORMANCES

Caution: the data presented do not represent the operating specifications of the kit, but serve as experimental proof of how the kit works within these specifications in the manner envisaged by the manufacturer.

Precision and Reproducibility

The precision and the reproducibility of the TGS TA TOXO IgG kit have been assessed using a protocol based on the guidelines given in Clinical and Laboratory Standards (CLSI) document EP5-A2.

The ***precision*** was calculated by analysing the results of 20 replicates of three sera performed with two different lots of reagents in the same test run.

The table shows the results obtained with the three sera.

Sample	Reagent Lot. no.	Mean Index	SD Index	CV %
1	2	0.423	0.042	9.9
	3	0.442	0.056	12.7
2	2	0.447	0.068	15.2
	3	0.482	0.035	7.3
3	2	0.363	0.054	14.9
	3	0.376	0.050	13.3

The ***reproducibility*** was calculated by analysing the results of the determination of five sera (at different levels of anti-Toxoplasma gondii IgG avidity) performed in 17 different sessions, with three lots of reagents.

The table shows the results obtained with the five sera.

Sample	Mean Index	SD Index	CV %
1	0.449	0.052	11.6
2	0.390	0.049	12.6
3	0.441	0.050	11.3
4	0.390	0.047	12.1
5	0.322	0.047	14.6

Analytical Specificity: Interferences

A study based on the guidelines given in the CLSI document EP7-A2 has shown that the dosage performances are not influenced by the presence in the sample of the potentially interfering substances listed in the table below, up to the tested concentration.

Potentially Interfering Substances	Maximum tested concentration
Free bilirubin	20 mg/dL
Conjugated bilirubin	20 mg/dL
Haemoglobin	1000 mg/dL
Triglycerides	3000 mg/dL

Use of lipaemic, haemolysed and turbid samples is not in any case recommended.

Relative Sensitivity and Specificity

The avidity index of IgG anti-Toxoplasma gondii antibodies was determined using the TGS TA TOXO IgG Avidity kit and an immunochemiluminescence assay available on the market in 98 samples.
7 samples gave rise to discordant results between the TGS TA assay and the other available method.
*The **global relative agreement*** was therefore found to be 92.9 % (95% Confidence Interval: 85.3%– 96.8%) (91/98).
*The **relative agreement*** in **low avidity** samples was found to be 80.6 % (95% Confidence Interval: 63.4%–91.2%) (29/36). Among 7 discordant samples, 5 samples have shown moderate avidity and 1 sample have shown high avidity.
*The **relative agreement** in **high avidity** samples* was found to be 100% (95% Confidence Interval: 92.7 – 100.0 %) (62/62).

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